Regulatory Updates on Medical Devices in Japan

- Amendment of Pharmaceuticals and Medical Devices Act (PMD Act) -

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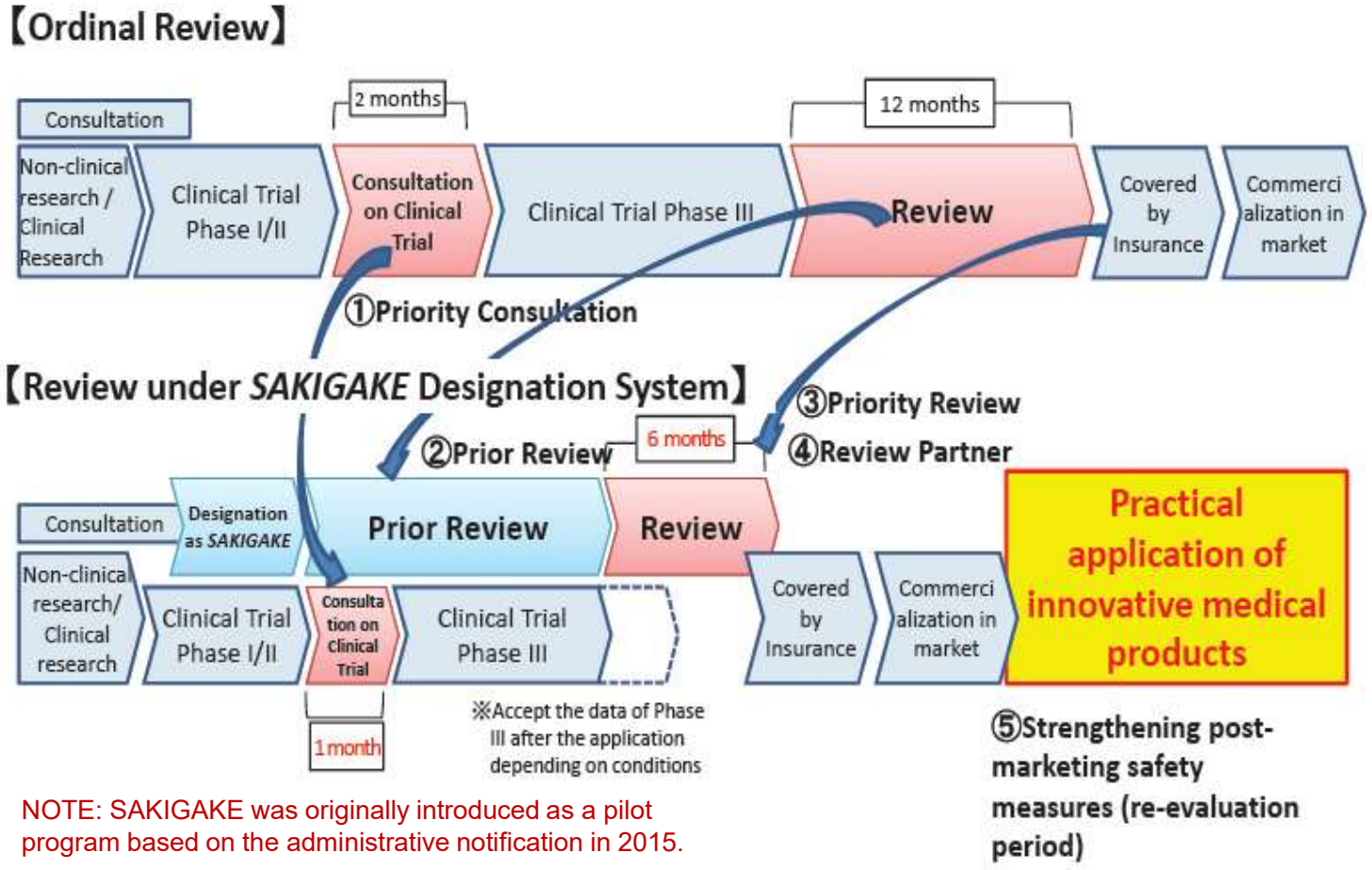
Overview of Amendment of Pharmaceuticals and Medical Devices Act (PMD Act)

- Enacted in November, 2019
  Implemented in September, 2020
- Following provisions are introduced :
  1. SAKIGAKE designation system
  2. Priority review for specific uses, e.g. pediatric use
  3. Conditional early approval system
  4. Post-Approval Change Management Protocol (PACMP) for Medical Devices

1. SAKIGAKE Designation System



NOTE: SAKIGAKE was originally introduced as a pilot program based on the administrative notification in 2015.

Administrative notification No.0831-6, August 31, 2020

Criteria and Advantage of SAKIGAKE Designation

➢ Criteria

- innovativeness
- severity of disease
- prominent effectiveness or/and safety
- willingness and framework to first development in Japan

➢ Advantage

- Prioritized Consultation: waiting time; 2 months →1 month
- Pre-application Consultation: de facto review before application
- Prioritized review: targeting total review time; 12 months → 6 months
- Review Partner: assignment of PMDA manager as concierge

Approved Products under SAKIGAKE Designation

➢ Products designated as SAKIGAKE

- Medical devices: 12
- In Vitro Diagnostics (IVDs): 2

➢ Approved Products under SAKIGAKE system

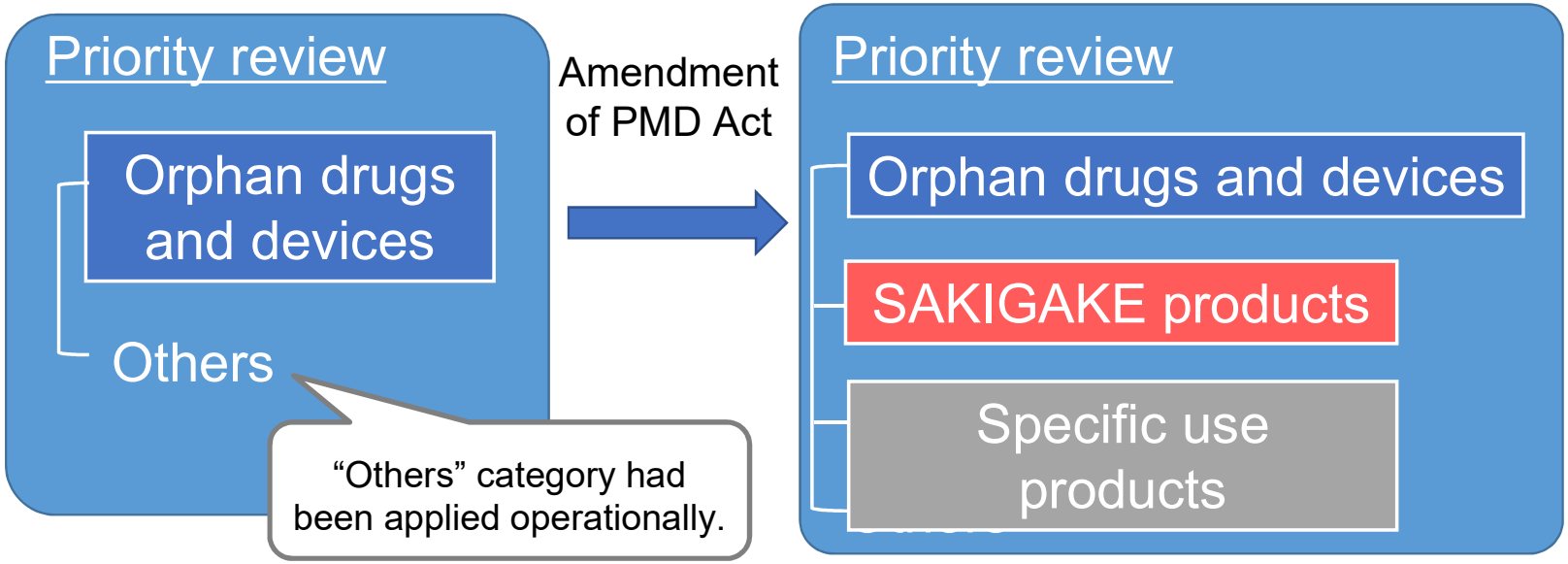
Category	Product name	Company	Indication	Date of designation	Approval date
Medical Device	TITANBRIDGE	Nobelpharma Co. Ltd.	Adductor spasmodic dysphnia	Feb. 10, 2016	Dec. 15, 2017
Medical Device	Boron neutron capture therapy(BNCT) system	Sumitomo Heavy Industries, Ltd.	Head and neck cancer	Feb. 28, 2017	Mar. 11, 2020
IVD	OncoGuide NCC Oncopanel System	Sysmex Corporation	Solid tumors	Feb. 28, 2017	Dec. 25, 2018

NOTE: These were approved as a pilot program based on the administrative notification in 2015.

2. Priority Review for Specific Uses

- Designation of “Specific use product” for highly unmet medical needs (e.g. pediatric use).
- Priority review and other supportive measures are applied to designated products for specific use.

Administrative notification No.0831-5, August 31, 2020



Criteria for Specific Use Products Designation

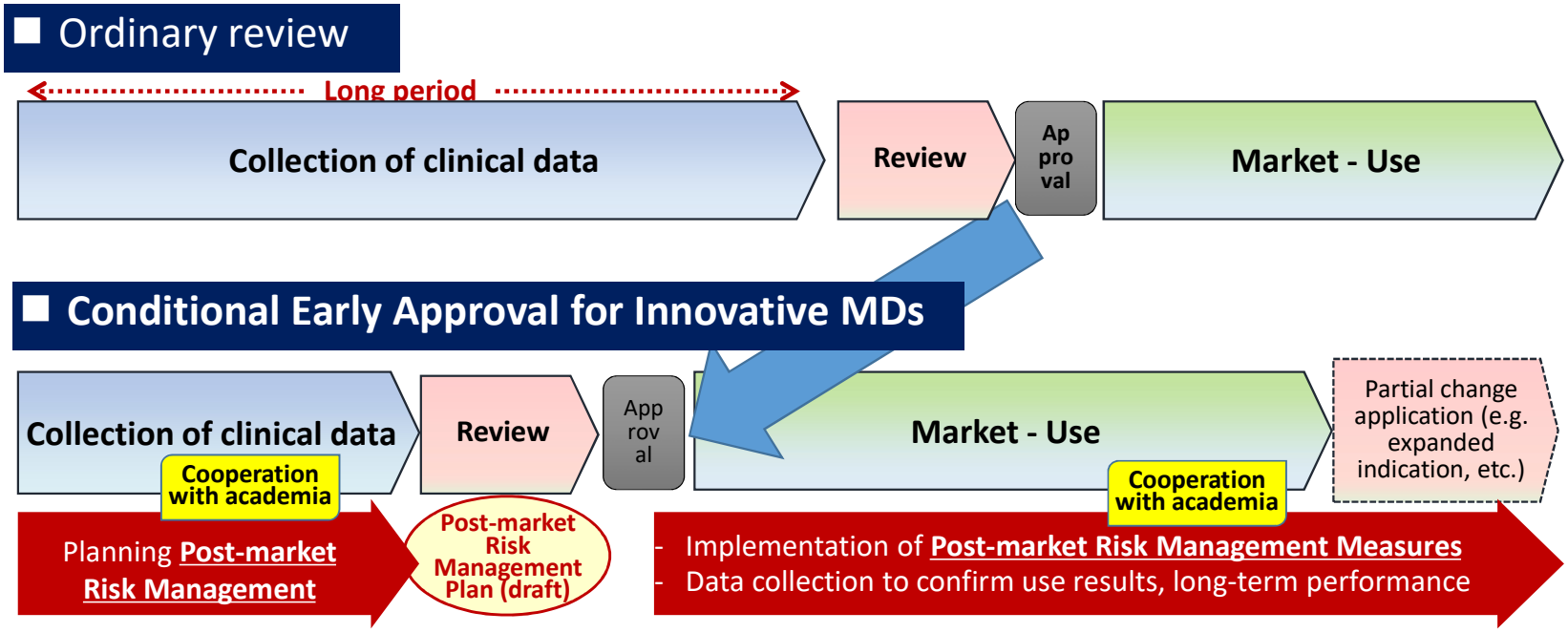
- **Criteria**
  - use for diagnosis, treatment or prevention of illness for children
  - highly unmet medical needs
  - excellent effectiveness and safety

- **Advantage**
  - Prioritized Review: targeting review time; 12 months → 9 months
  - Tax benefits and grants of subsidy for product development

3. Conditional Early Approval System

Accelerate approval of MDs of high medical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

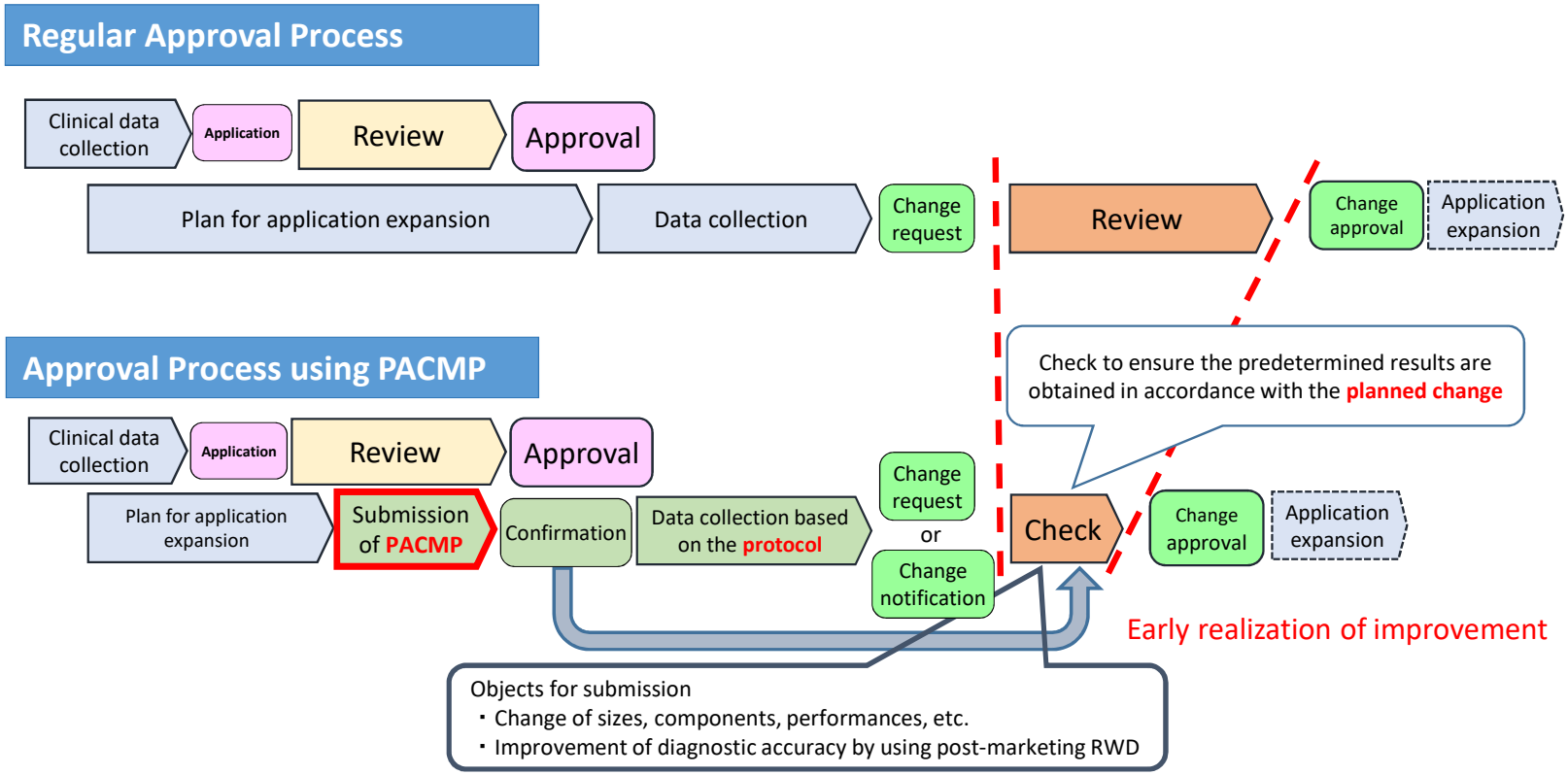
Administrative notification No.0831-2, August 31, 2020



4. Post-Approval Change Management Protocol (PACMP)

PACMP is introduced for medical devices to enable continuous improvements through product lifecycle.

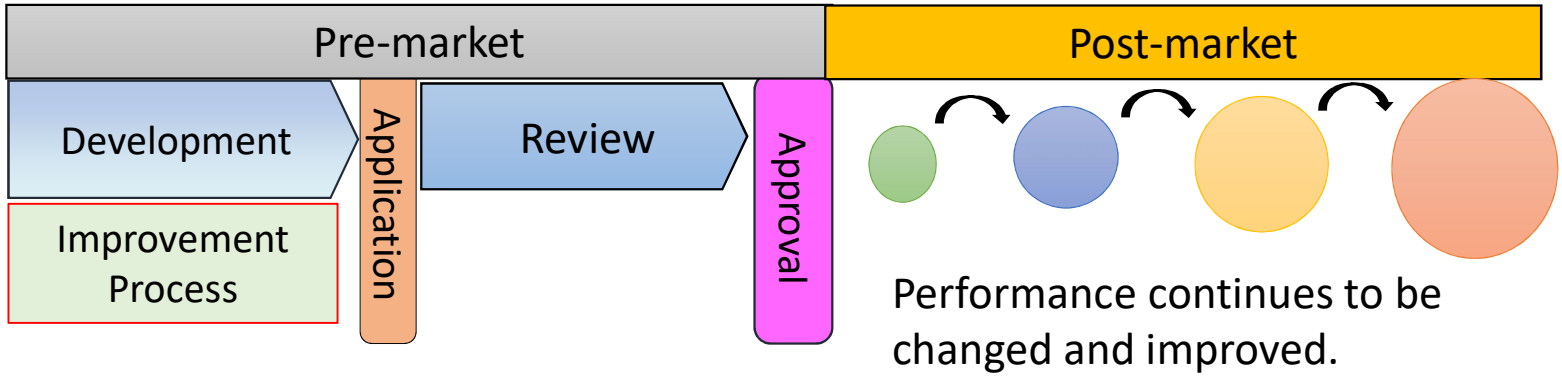
Administrative notification No.0831-14, August 31, 2020



PACMP for AI medical devices

Approval review process which enables continuous improvement of performance of SaMD using AI

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes as “Improvement Process”, and submit in the approval review process.



Thank you for your attention!